EXHIBIT F

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327

MDL NO. 2327

JOSEPH R. GOODWIN
US DISTRICT JUDGE

THIS DOCUMENT RELATES TO:

Iretta Lynn Ashbrook v.
Ethicon, Inc., et al.
Case No. 2:13-cv-10672

- - -

OCTOBER 22, 2019

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Deposition of LENNOX HOYTE, MD, held at Morgan & Morgan, PA, 20 North Orange Avenue, Suite 1600, Orlando, Florida 32801, commencing at 9:16 a.m., on the above date, before Joan L. Pitt, Registered Merit Reporter, Certified Realtime Reporter, and Florida Professional Reporter.

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GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

APPEARANCES:

Counsel for the Plaintiff:
JOSEPH M. TARASKA, ESQUIRE
Morgan & Morgan, PA
20 North Orange Avenue
Orlando, Florida 32801-2414
407.420.1414
jtaraska@forthepeople.com

Counsel for the Defendants:
DAVID B. THOMAS, ESQUIRE
Thomas Combs & Spann PLLC
300 Summers Street, Suite 1380
Charleston, West Virginia 25301
304.414.1807
dthomas@tcspllc.com

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THE COURT REPORTER: Raise your right hand, please. Do you swear or affirm the testimony you give will be the truth, the whole truth, and nothing but the truth?

THE WITNESS: I do.

THE COURT REPORTER: Thank you.

LENNOX HOYTE, MD, called as a witness by the Defendants, having been first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. THOMAS:

Q. Good morning, Dr. Hoyte.

A. Good morning.

Q. My name is David Thomas. I represent Ethicon in the Ashbrook case pending in the multidistrict litigation in West Virginia.

I understand you're an expert witness for Ms. Ashbrook; is that correct?

A. I am.

Q. Would you state your full name for the record, please?

A. My name is Lennox Hoyte.

Q. And Dr. Hoyte -- it is Dr. Hoyte; correct?

A. Correct.

(Hoyte Exhibit No. 1 was marked for identification.)

BY MR. THOMAS:

Q. I have a CV that's been supplied to me that I'll mark as Deposition Exhibit No. 1. Is this CV complete and accurate to the best of your understanding?

A. Yes. It says December 2018, and I believe it's correct.

Q. Okay. Is it your practice to upgrade -- or update your CV on a regular basis and add information as it becomes relevant to your CV?

A. That mattered when I was in academics, and I'm no longer in academics. I left in 2016. So I'm not as exact as updating, but this is substantially correct.

Q. Okay. Have you ever removed anything from your CV over the years?

A. I don't think I would have removed publications or presentations, but I may have altered the narrative from time to time.

Q. Okay.

A. I don't recall specifically.

Q. You received the notice of deposition for this case. Have you seen the notice?

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A. Yes, sir.
Q. Did you seek to bring information to the deposition responsive to the notice of deposition?
A. I gave all the information to counsel.
MR. THOMAS: And, Counsel, did you bring stuff for me?
MR. TARASKA: I brought stuff for you. Here's a copy of Dr. Hoyte's expert testimony.
MR. THOMAS: Let me just do this. I really don't want to spend a lot of time on this because I'm not --
MR. TARASKA: Sure.
MR. THOMAS: Yeah. And let me ask you this: To the best of your knowledge, is there anything that you were unable to provide other than the two cases that you mentioned by e-mail yesterday?
MR. TARASKA: Yeah, that I spoke with Amy about?
MR. THOMAS: Right.
MR. TARASKA: Other than the invoices and the reports that had to do with that, I think we've got everything. I think I've got it all.
MR. THOMAS: Good.
MR. TARASKA: The medical records are in the

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back, and we'll have to pull those for you.
MR. THOMAS: I hope that we don't have to get into those in any detail.
MR. TARASKA: All right. Good.
MR. THOMAS: If we get to that point, then I'll have to ask about it.
MR. TARASKA: Go ahead.
BY MR. THOMAS:
Q. In the materials that you gave to counsel, did you include your billing records for this case?
A. Yes, sir.
MR. THOMAS: I do want to see those, Joe.
MR. TARASKA: Sure. Ashbrook and Ashbrook.
(Hoyte Exhibit No. 2 was marked for identification.)
BY MR. THOMAS:
Q. Doctor, counsel's given me some records I'll show you. The first record is dated August 3, 2019. I've marked that as Deposition Exhibit No. 2. What does that represent?
A. It looks like a bill to Attorney Taraska regarding Iretta Ashbrook for activities performed related to the Ashbrook matter.
Q. Do you mind if I look over your shoulder and

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read with you?
A. Not at all.
Q. Thank you. You charged a $10,000 retainer to review the records in this case; is that right?
A. Correct.
Q. Okay. And the entries on Exhibit No. 2 represent the time that you spent reviewing records and preparing your expert report?
A. Correct.
Q. And you charged $1,000 an hour for your time?
A. Correct.
Q. Do you charge the same for your deposition time?
A. Today's deposition, being audio, it's the same rate, with a three-hour minimum.
Q. So in April 2019 you spent approximately seven hours drafting the expert report?
A. Correct.
Q. Do you have anybody that assists you in your review of medical records and preparation of reports in this case outside of counsel?
A. I don't understand the question.
Q. Sure. Did you do all this work by yourself?
A. Personally, correct.

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Q. Thank you. The second page -- it seems like this is the same thing. That's what I was looking at.
A. Okay.
Q. It's not the same thing.
A. Yes. Yes. Okay. If you ask me a question, I'm happy to answer.
Q. Sure. Second page of page 2 shows additional charges for September 2019?
A. Correct.
Q. When you reviewed the case-specific defense expert report, that's Ethicon's expert?
A. Correct.
Q. For $2,000?
A. Correct.
Q. And then a second --
A. I can explain that.
Q. Yeah.
A. If you'd like.
Q. Does this document relate to Ashbrook?
A. So there are two activities. So as you may be aware, there are multiple things that we're talking about today.
Q. Right.
A. And there's a general expert defense report by

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Dr. Kenton and by Dr. Sirils that applies equally to all three.
Q. I see.
A. So I think there was a total for this that I think was divided between Ashbrook and the other matters.
Q. Perfect.
A. So this -- a third of this should apply to Ashbrook.
(Hoyte Exhibit No. 3 was marked for identification.)
BY MR. THOMAS:
Q. So I'm going to mark that as Deposition Exhibit No. 3.
A. If you don't mind putting an E at the end of my name, I'd be grateful.
Q. We'd be happy to.
A. That happens a lot.
Q. Well, I apologize for that. We'll fix that.
So just so the record's clear, Deposition Exhibit No. 2 contains all of the charges through September 25, 2019. They're specific to the Ashbrook case?
A. Yes.

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Q. And Exhibit No. 3 contains four hours of time that you spent reviewing the general expert reports of Drs. Kenton -- I think that's Dr. Sirils --
A. Correct.
Q. -- of $4,000 that's to be spread among different cases?
A. Correct.
Q. All right. Do Exhibit Nos. 2 and 3 represent the total of your billings for the Ashbrook case?
A. To date, invoices that I've submitted, correct.
Q. Okay. Today is October 22?
A. Correct.
Q. What work have you done since your last invoice?
A. So prepared for this deposition, reviewed additional materials, which I haven't yet tabulated.
Q. Okay. What other materials have you reviewed?
A. I think there was a deposition of the implanter. There may have been additional records, and I can't remember specifically.
Q. Okay.
MR. TARASKA: Can I help you with one thing?
MR. THOMAS: Sure.
MR. TARASKA: We did forward to Dr. Hoyte the

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report that we submitted, the Rule 26 report of Mrs. Carruthers, who did the life care plan.
MR. THOMAS: Okay.
MR. TARASKA: So that would be something also.
BY MR. THOMAS:
Q. And what did you do to prepare for your deposition?
A. Reviewed the medical records, reviewed my Rule 26, I reviewed additional medical records that were sent to me that I looked at, and I believe there were depositions as well.
Q. I don't have a deposition of an implanter in this case. Do you have a specific recollection of reviewing an implanter's deposition?
A. Again, I apologize. I have the three matters that are stuck in my head, so I don't --
Q. And, Doctor, let me tell you something that may help you understand. As you know, there are thousands of these cases, and I don't work on cases individually. They've asked me to come in and take the depositions of you as an expert, and I very often learn that you have stuff that I don't have. So -- just so -- there's no tricks here. I'm just trying to figure it out.
A. Yeah. I'm happy to give you a record of

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everything that I've worked on, and I can send that, and I think counsel has it. He sent me the information. He can give that to you.
Q. My only message to you is I don't have an implanter's deposition. That doesn't mean it wasn't taken and you've reviewed it.
A. I'm going to say deposition.
Q. Okay. That's fine.
A. I'm happy to give it to you.
Q. I understand that. I'm just making sure we're talking about the same thing.
A. I'm not trying to hide anything from you. I'm just --
Q. And neither am I.
A. Yeah.
Q. For the work that you've just described that you've done since your invoices described in Exhibits No. 2 and 3, can you tell me generally your best recollection of how much time you spent prior to your deposition today?
A. I don't have a number in my head.
Q. Do you keep track of your time?
A. I try to by individual pieces, but I don't have a tabulation.

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Q. Do you write it down?
A. Somewhere, yes.
Q. Okay. So somewhere there's a written record of the time you spent on the Ashbrook case between Exhibits 2 and 3 and today?
A. Somewhere there may be.
Q. Okay.
A. And I think by the time this is all over, within the next few days, there will be a tabulation of the total time spent that you're happy to -- I'm happy to send to counsel of record.
MR. TARASKA: And I will forward that to you.
MR. THOMAS: Great.
(Hoyte Exhibit No. 4 was marked for identification.)
BY MR. THOMAS:
Q. Let me show you now what I'm going to mark as Deposition Exhibit No. 4. Deposition Exhibit No. 4 is a copy of the report that's been supplied to us. Do you recognize that as your report?
A. I do.
Q. In the Ashbrook case?
A. With the appropriate correction of my name. It's H-o-y-t-e.

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Q. Let's do that right now just so we fix that. I apologize for that.
A. I know the version without an E is a very Southern name, and so I'm not surprised that a good Southern gentleman like yourself might make some assumptions.
Q. Where do you think I'm from, Doctor?
A. You sound to me like a fine Southern gentleman.
Q. Well, that's nice of you to say.
A. That's all I'm going to say.
Q. My home's West Virginia.
A. That's the South, isn't it?
Q. Well, it depends on who you ask. It depends on who you ask.
And, Doctor, your report, Deposition Exhibit No. 4, is that a complete representation of the opinions you're prepared to give in this case?
A. I think the opinions I expressed herein are generally complete. If I could, I would tell you that I've said in the end here that the prognosis is uncertain, and I would basically want to clarify that. Otherwise, I would say it represents my opinions.
Q. Okay. And we'll get to that, so I will give you that chance.

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A. I appreciate it.
Q. Do you have any further work that you're prepared to do on the Ashbrook case beyond what you've expressed in your report?
A. As I've said, I'm reserving the right to augment my report as more information, data findings become available.
Q. Okay. Anything in particular you have in mind?
A. Well, I wouldn't have it in mind if it wasn't before me, so it would have to come before me.
Q. Okay.
A. And then I --
Q. There's nothing that you plan to do with respect to the Ashbrook report until something's brought to your attention; is that fair?
A. I think that's what I said, yeah.
Q. Okay. Doctor, there are three depositions today: The Messina case, the Ashbrook case, the England case. A lot of the questions that I'm going to ask will apply to all three. I'm going to try to avoid duplication, but so know that when I ask you questions about general information, it may apply equally to the other two cases as well.
A. I'm not sure I understand.

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Q. Sure. I'm going to talk to you a little bit about your background and history --
A. Correct.
Q. -- in Ashbrook.
A. Correct.
Q. I may not ask you about them in Messina and England, but whatever you say in the Ashbrook case will apply equally to Messina and England.
A. I'm just going to ask you gentlemen --
MR. TARASKA: That's acceptable.
MR. THOMAS: I'm just trying to avoid duplications.
MR. TARASKA: That's good, yeah.
BY MR. THOMAS:
Q. Okay. Let's look at page 3 of Exhibit No. 4, please.
A. Yes, sir.
Q. If you'd look at page 3 in the first full paragraph beginning: "The only mesh procedures that I perform are abdominal (open and robotic) sacrocolpopexies, and the only types of incontinence slings that I place are large pore, low stiffness retropubic slings."
Prior depositions that I reviewed suggest that

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your current sling of choice is the Caldera Desara. Is that still your sling of choice?
A. That's currently the only sling that I use --
Q. Okay.
A. -- for urinary incontinence.
Q. Okay. And --
A. Synthetic sling.
Q. And how long have you used the Caldera Desara sling?
A. Many years.
Q. Ten?
A. I can't say.
Q. Okay. Are you suggesting that had you used the Caldera Desara sling for the treatment of the SUI experienced by Ms. Ashbrook that she would not have suffered the complications that are the subject of this claim?
A. I'm saying that the complications that Ms. Ashbrook -- Ms. Ashbrook suffered are related directly to the fact that she had a transobturator transversely placed, transversely anchored sling placed that caused her specific complaints that would not have occurred if these were a retropubic sling that she had placed because of the difference in trajectory.

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Q. Okay. So are you saying that if the surgeon had used an Ethicon TVT midurethral sling placed retropubically, the TVT Classic, that she would not have sustained the injuries that she claims in this case?
A. I'm saying that, again, her injuries relate to the fact that she has a transversely placed, transversely anchored midurethral sling placed. That would not have occurred if she had a retropubic sling placed.
Q. And if you -- as you use retropubic sling, does any retropubic sling solve her problems?
A. I don't understand.
Q. Sure. There are a number of slings that are manufactured that are placed retropubically. Do you agree with that?
A. I know of a few.
Q. And I guess the Desara can be placed both through the transobturator or retropubically; correct?
A. I've never placed a transobturator. I understand that they do have helical passers, which I've never used or seen personally. I've heard that they have helical passers for retro -- for a transobturator placement.
Q. So what midurethral slings do you know can be

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placed retropubically?
A. I know that the Desara can, and I know Boston Scientific has a sling that can be placed retropubically.
Q. Do you know the name of the Boston Scientific sling that can be placed retropubically?
A. I do not have it off the top of my head.
Q. If -- if the surgeon had chosen the Boston Scientific sling and placed it retropubically, would Ms. Ashbrook have the complications that she presents with today?
A. Ms. Ashbrook would not have groin pain and difficulty moving her lower limbs if she had a retropubic sling placed properly.
Q. Would she have any of the complications that she presents with today if she'd had a synthetic midurethral sling placed retropubically?
A. Okay. We'd have to go over the complications list in order to line-by-line that if you would like.
Q. Okay. Let's go to page 25 of your report. Down about three-quarters of the way down, it says: "In my opinion, her chronic pelvic pain, groin pain and dyspareunia occurred because of the scarring of the Gynecare TVT-Obturator mesh into the anterior vaginal

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wall and pelvic floor."
My question is: Had the surgeon, implanting surgeon, placed a synthetic midurethral sling retropubically, would she have experienced chronic pelvic pain, groin pain and dyspareunia?
A. She would not have experienced chronic pelvic -- groin pain, obturator pain and groin issues, and she would be highly unlikely to experience dyspareunia as a result of a retropubically placed synthetic midurethral sling.
Q. Okay. Is it your opinion that there is a higher risk of dyspareunia from a retropubically placed synthetic midurethral sling as compared to a synthetic midurethral sling placed through the transobturator?
A. So I'm not sure that you want to ask that question, but you're asking me if the retropubic sling has a higher rate of dyspareunia? That's what you asked?
Q. Well, you're correct. Thank you.
A. That's okay.
Q. Doctor, is it your opinion that a synthetic midurethral sling placed through the transobturator has a higher incidence of dyspareunia than a synthetic midurethral sling placed retropubically?

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A. Yes, and there's an anatomic explanation for that.
Q. Okay. Is that based on your review of the literature?
A. That is my -- based on my review of patients who have undergone transobturator slings.
Q. And that's based upon your clinical experience?
A. Clinical experience with patients and anatomic explanation to justify and explain this.
Q. Do you have any published literature to support your position on that topic?
A. I'm a case-specific expert, and I'm here to talk to you about Ms. Ashbrook. I'm telling you about the anatomy that is relevant to the placement of the transobturator sling. It punctures the levator ani, the obturator internus, and the adductor muscles. It causes pain. It causes spasm in the levator ani muscles, spasm in the levator anatomy, and increased amounts of pain with intercourse penetration that does not happen with retropubic slings.
Q. My question, Doctor, though: Do you have any literature to support for your position that the risk of dyspareunia is greater with a transobturator midurethral sling as opposed to a retropubic midurethral sling?

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A. So I was brought here as a case-specific expert. I was not asked to review literature. I was asked to evaluate Ms. Ashbrook and her symptoms. So I'm not prepared to talk to you about literature.
Q. Okay. Back on page 5 of your report, about three-quarters of the way down, you say, "I have reviewed the general and product-specific literature related to the Gynecare TVT-O product."
What does that mean?
A. So the Gynecare TVT-O product has information related to the product, the Instructions for Use that I have reviewed.
Q. Okay. When you say "product-specific literature," does that exclude scientific studies on the TVT-Obturator?
A. I don't say that it excludes scientific studies because my background, information set based on my continued ongoing CME learning, medical learning, training, and generalized keeping up with my field requires that I keep current with literature.
Q. Have you ever published on the midurethral slings implanted transobturator -- through the transobturator?
A. Personal publications?

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Q. Yes.
A. I have not.
Q. Have you ever studied personally the implantation of midurethral slings through the transobturator?
A. Studied in detail the Instructions for Use, studied in detail the anatomy, and the trajectory of placement, yes.
Q. Okay. Have you ever participated in a study where a cohort of patients were followed for their response to implantation of a transobturator midurethral sling?
A. I have not participated in such a study.
Q. Do you know whether or not the Desara sling system was available at the time of the Ashbrook implant surgery in October of 2010?
A. I do not know.
Q. Were you implanting midurethral slings for the treatment of stress urinary incontinence in 2010?
A. I was.
Q. Do you know what sling you were using in 2010?
A. I can't say for sure, but probably likely the Desara if it was available, but I can't commit to that.
Q. We spoke a minute ago that the only

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incontinence slings that you place are large pore, low stiffness retropubic slings. What significance is the large pore aspect of that statement?
A. Large pore meshes have lower risk -- have a higher ability for tissue ingrowth, a lower risk of scar plate formation, which tends to be painful, and a better integration into tissue. They drape with tissue better.
Q. Is it fair to say the larger the pore in the midurethral sling, the better tissue integration you get?
A. The larger the pore, the better tissue? I just know larger pore slings behave better in tissue settings.
Q. Okay. What's the significance of the low stiffness statement in your report, the fact it's low stiffness?
A. I think there's some understanding that we've come by over the years that the higher stiffness the material is, it tends to force the surrounding tissue to conform to the material rather than the other way around. We want the stiffness to be more in line with the surrounding tissue so that the foreign body drapes to the tissue and not the other way around. So low stiffness matters for that reason.

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Q. Do you know how the pore size of the Desara sling compares to the pore size of the TVT-O?
A. Again, I'm case specific, so I don't have that information on the top of my head. I didn't research that for this presentation.
Q. Do you know how the stiffness of the Desara sling compares to the stiffness of the TVT-O?
A. I do not.
Q. Doctor, you've told me that you understand the Desara sling can also be implanted retropubically -- excuse me. Strike that.
Doctor, you've told me, I believe, that the Desara midurethral sling can also be implanted through the transobturator space; correct?
A. I've never seen it done myself.
Q. Do you know that it can?
A. I am familiar with the fact that they advertise helical passers, which to me suggests that there may be a transobturator version. I've never asked about it. I've never seen it. I've never seen it performed.
Q. Is it your opinion that a Desara sling implanted through the transobturator can cause the same symptoms that Ms. Ashbrook has presented with in this case?

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A. I think I've said before that Ms. Ashbrook's symptoms are related to the trajectory of the mesh that she had placed. So the trajectory is a side to side going through the levator ani, obturator internus, obturator externus, adductor magnus, and groin tissues. The sling placed in that trajectory would create very likely the kinds of complications Ms. Ashbrook had.
Q. And do you know the trajectory of the Desara sling system when its placed through the transobturator?
A. Again, I've said I've never seen placement of a Desara sling. I've not read the IFU for transobturator placement of the Desara sling. I have read the IFU for the transobturator placement of the TVT-O, and that goes through the muscles and tissues that I described earlier.
Q. And the Desara sling is polypropylene?
A. Yes.
Q. And is the TVT-O polypropylene?
A. That is my best understanding.
Q. Do you have any complaint with the materials used in the TVT-O device?
A. I use polypropylene in other applications such as the Desara sling and sacrocolpopexy mesh. Therefore, I do not have complication -- I'm sorry, I do not

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have -- I'm sorry, what was your question?
Q. You don't have any complaints about the materials?
A. About polypropylene as a material, I do not.
Q. Okay. Do you have any information that the pore size of the TVT-O is larger than the Desara?
A. I don't have that information.
Q. Do you have any information that the TVT-O is less stiff than the Desara?
A. I don't have that information.
Q. Those would be good things as far as you're concerned?
A. What would be good things?
Q. Large pore size and less stiff.
A. I think that's what I said earlier in my report regarding retropubic slings.
Q. You also say that you like to have large pore polypropylene slings which come enclosed in plastic sheaths designed to protect the sling materials from the vaginal fluids and bacteria during placement. That's on page 4 of your report.
Do you know the TVT-O comes enclosed in a plastic sheath? Did you know that?
A. I'm sure it does.

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Q. Is the use of the sling with a TVT-O any different from the use of the sling in the Caldera sling that you use?
A. I don't understand the question.
Q. Sure. Is there any difference in the sheath on the TVT-O as compared to the sheath on the Caldera sling that you use?
A. So since I haven't analyzed the TVT-O in comparison to the Caldera, I would have to trust that Ethicon would make a plastic sheath, if they're making it, that would be satisfactory.
Q. Do you know whether Ethicon used the plastic sheath before Caldera did?
A. I would have to say that Johnson & Johnson/Ethicon has been making slings before Caldera was making slings, and if I believe that statement, then I believe Johnson & Johnson has had a sheath in the earlier slings. That's from my recollection.
Q. Okay. Let's go to page 8 of your report, please. Page 8 of your report has a paragraph that begins: "When I evaluate, diagnose, and treat women."
This is the methodology that you use to diagnose and treat a patient; is that fair?
A. Yes. When a patient comes to me in my -- in a

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clinical setting, yes.
Q. And you say you usually rely on an interview with the patient; correct?
A. In a clinical setting, correct.
Q. You've not interviewed Ms. Ashbrook in this case; correct?
A. I've not talked to Ms. Ashbrook.
Q. A review of her personally documented history. Do you have a personally documented history from Ms. Ashbrook?
A. I have her medical records with her questionnaires that she completed.
Q. Do you have anything that she personally documented her history for you?
A. Not for me personally. I have not talked to Ms. Ashbrook.
Q. And you reviewed her medical records?
A. I did.
Q. And a detailed clinical examination when possible. You've not been able to do a detailed clinical examination; is that fair?
A. I did not. She was not my clinical patient.
Q. If she was your clinical patient, you'd like to do all four of these before you would diagnose and treat

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her; correct?
A. When a patient comes to me for clinical care and treatment and management, I do these things.
Q. Okay. A few minutes ago you told me that you'd like to correct something in the report or supplement something in your report about her prognosis?
A. Correct.
Q. I believe you said her prognosis was uncertain?
A. Correct.
Q. What would you like to say about that in addition to your report?
A. So I would like to say that as a care provider, as a doctor, my job -- and I believe it's my role to give hope to patients and look for ways to cure them, and so that is my bias or my intent. When I reviewed Ms. Ashbrook's case and I think about the totality of patients that I've seen, I would say that it's highly unlikely that Ms. Ashbrook is going to be cured permanently of her symptoms, that her symptoms and complaints are likely -- more likely than not to be permanent.
Q. Is that a medical opinion to a reasonable degree of certainty?
A. Yes, sir.

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Q. How can you give that opinion without interviewing her and doing a detailed clinical examination, which is your normal methodology?
A. So what I've said before is that in a multitude of patients that I've seen with similar conditions to Ms. Ashbrook, who I've evaluated, it is highly unlikely that those patients stand to be permanently cured. Ms. Ashbrook's history, physical presentation and symptoms as documented and evaluated by competent physicians confirm for me that she is substantially similar to patients that I've seen. I've seen patients just like her, and she is unlikely to be permanently cured.
Q. You've never met Ms. Ashbrook?
A. I have not.
Q. You've not read any depositions of any treating physicians for Ms. Ashbrook?
A. I can't tell you that I have or have not, because I don't have that information off the top. I did read in detail the physicians' records.
Q. And you don't have any recollection of reading the deposition of Ms. Ashbrook, do you?
A. I believe I read her deposition, I think that's on the form that you talked about.

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Q. Not in your report?
A. I'm sorry?
Q. There's no -- there's no reference to her deposition in your report.
A. But I did read her deposition. It's -- I think it's in the invoices.
Q. Okay. What is it about what you read in her deposition that causes you to believe that she's highly unlikely to recover from her symptoms?
A. I'm reviewing the records of the physicians who have treated her over the course of multiple treatments. I think she's had a number of surgeries, and she continues to have complaints.
Q. Okay.
A. Up until the last -- after six surgeries, getting Procedure No. 8 by Dr. Reynolds, she continues to have retention, recurrent vaginal pain, recurrent UTI, dyspareunia, and chronic constipation. Her symptoms persist. It's like seven interventions -- like eight interventions. The likelihood of her getting cured after another -- eight interventions is extremely low. It's more likely than not her symptoms are permanent.
Q. What kind of pain medications does Ms. Ashbrook

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take currently?
A. I would have to look at that with you in the record.
Q. Okay. Do you know whether she's ever had injections for pelvic pain?
A. We can look and see here. Cystoscopy. She's had Botox injection of the bladder. She's had multiple of those.
Q. Are those for pain?
A. Botox injections is for overactive bladder. Left groin pain, paresthesias, constipation. I don't see any injections.
Q. Okay. Is Ms. Ashbrook sexually active?
A. I do not know the status, but she did report that she felt pain with sexual intercourse.
Q. Do you know the last time she had pain with sexual intercourse?
A. I would not know since I've not asked her that question.
Q. And you're aware she has a hernia?
A. Shall we look and see where that is?
Q. Do you recall that she has a hernia?
A. I recall a hernia in one of my reviews for today, but I would have to have you show me that.

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Q. Okay. Doctor, let's talk about your chronology that begins on page 8 of your report. How did you go about preparing this chronology?
A. I reviewed in detail Ms. Ashbrook's medical records from 12/16/2009 relevant to her pelvic floor issues all the way up through the most current record I have, which is on 11/01/2018 with Dr. Reynolds. So I reviewed the medical records and I make -- I developed a chronology from the medical records.
Q. And what did you deem relevant to put in your chronology?
A. Medical records that I have related to Ms. Ashbrook's pelvic issues, issues between the belly button and the upper thighs. I did not focus on her thyroid disease or breast reduction, for example. I took records related to her pelvic floor complaints.
Q. All right. If you go to page 9 of your report, I think that's Exhibit No. 4, we have an implant on October 29, 2010, by Dr. Viner; correct?
A. Yes, sir.
Q. And then other than an auto crash, the next entry you have is on June 14, 2010, where there's a revision of that TVT-O implant; correct?
A. Can you say the date that you're referring to,

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please?
Q. June 14, 2012.
A. Yes, sir.
Q. Do you know what happened in the year and a half between October 29, 2010, and June 14, 2012, that caused the revision surgery to take place?
A. Well, in 6/14/2012 Ms. Ashbrook has reported as having dyspareunia and stress incontinence as well as a sebaceous cyst. I would think that dyspareunia and stress incontinence -- that developed during that period of time and stress incontinence persisted.
Q. No evidence of erosion or exposure, is there?
A. Between 2010 and 2012 I don't see that matter discussed here.
Q. You don't have any other information that suggests that she had an erosion or exposure of her TVT-O between the implant on October 29, 2010, and the procedure with Dr. Windisch and Dr. Case on June 14, 2012?
A. I don't have any documentation of that.
Q. So in your -- based on your review of the medical records, what were the indications that suggested that removal of the sling was appropriate?
A. Procedure No. 2 described dyspareunia and the

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doctor who reviewed this believed that her dyspareunia was related to her sling. That would be the reason that I would remove it.
Q. Okay.
A. But I'm not that doctor.
Q. Okay. And your analysis of her situation may have been different?
A. If I examined her, I might have had a different opinion.
Q. And you may have had a different procedure if you differed with the opinions of Dr. Case and Dr. Windisch?
A. If I differed. I'm not sure I would have differed.
Q. Okay. What is it about her presentation on June 14, 2012, other than dyspareunia and stress incontinence suggests that the sling should be revised?
A. I think dyspareunia and stress incontinence in the setting of a retro -- a transobturator sling that a surgeon felt to be the source of the dyspareunia, I think is sufficient.
Q. Okay. Now, on page 10 you say that Dr. Windisch removed the transobturator vaginal sling and placed a pubovaginal sling using cadaveric fascia

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Repliform. Repliform is a brand name?
A. It's a type of cadaveric fascia.
Q. Okay. Is that a brand name of a manufacturer's cadaveric fascia that they sell?
A. I've heard that name before as a brand name. I've not used it myself.
Q. Okay. Did you determine whether, in fact, Dr. Windisch did remove the TVT-O on June 14, 2012?
A. So I was not asked to determine if he removed the TVT-O. His operative report says that that's what he did, and he described it in detail. And I would have here to depend on the pathology report from what he extracted to determine if he or she actually got the mesh material. It's been my experience that sometimes you think you have mesh and you don't.
Q. Okay. Well, let's look at the pathology report.
A. Okay.
Q. It's on page 10. Is there any mention of mesh?
A. There's not.
Q. Did you make any determination at all for purposes of your review of the medical records whether Dr. Windisch did, in fact, remove the Ethicon TVT-O during the surgery of June 14, 2012?

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A. Well, if he or she sent everything that they removed from the anterior vagina wall, the pathology report says there's no mesh identified. That indicates to me that what was sent to the pathologist did not contain mesh, if I believe the pathologist, of which I do.
Q. A little different question to you, Dr. Hoyte, and that is: Do you have an opinion as to whether Dr. Windisch removed the Ethicon TVT-O mesh during the procedure on June 14, 2012?
A. I do.
Q. What is the opinion?
A. It appears very likely that he did not.
Q. And also the Windisch operative report suggests that there was a placement of a pubovaginal sling using cadaveric fascia Repliform. Do you have an opinion as to whether Dr. Windisch did, in fact, place the pubovaginal sling using the cadaveric fascia?
A. I do.
Q. What is that?
A. From the operative report, he describes placing it. I believe it.
Q. Okay. So if your opinion is Dr. Windisch did not remove the TVT-O and did place a cadaveric sling,

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that means Dr. Windisch put the cadaveric sling on top of the TVT-O?
A. Not necessarily.
Q. What does that mean?
A. Well, the urethra is 3 to 4 centimeters long. The TVT-O is designed and called a midurethral sling, which implies that it's placed somewhere 2 to 3 centimeters distal to the bladder neck. Pubovaginal slings are usually placed at the bladder neck, which is a different location anatomically to the TVT-O. So it would be impossible to place a retropubic sling over a transobturator sling. They would collide.
Q. Okay. So is it your opinion that Dr. Windisch placed the pubovaginal sling in addition to the TVT-O sling that was already present?
A. He didn't place the TVT-O sling. Is that what you're saying?
Q. No. Did Dr. Windisch leave the TVT-O in? I think we decided that's what you believe.
A. I believe he did not remove it.
Q. Okay. So Dr. Windisch then placed the pubovaginal sling in addition to the TVT-O sling that was already there placed by Dr. Viner in October 2010?
A. I'm confused by the "in addition to." I'm

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going to say that this doctor of this patient had placed a pubovaginal sling and did not remove the previously existing transobturator sling.
Q. Thank you for clarifying my bad question. That's exactly what I wanted to understand. Thank you.
What are the risks of complications of having two slings in a person at the same time?
A. What are the risks of complications of having two slings at the same time? I have to tell you that I get a number of patients coming to my practice that have had second slings placed over initial slings. I personally would not do it, because what I've seen in those cases is that the two slings fight with each other, to use a medical term, and they tend to counteract the behaviors of each other. And so I'm not sure that that is something that I would do. Actually, I'm pretty clear that's not something I would do. I have seen lots of patients with transobturator and retropubic slings in place.
Q. And what kind of symptoms do those cause?
A. I don't know that I could tell you what kind of symptoms they cause. I've seen persistent stress incontinence in that setting.
Q. Well, it's fair to say if the goal of the 2014

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surgery was to remove the TVT-O because of the dyspareunia and stress urinary incontinence she complained of when she saw Dr. Windisch, that they didn't accomplish that?

A. They did not accomplish removal of the TVT-O sling I think is what I can safely say.

Q. And I think we also decided that the reason for the procedure was to remove the TVT-O to treat her dyspareunia and her stress urinary incontinence; fair?

A. So in looking at the diagnoses of dyspareunia and stress incontinence, I think the attempt at removal of the TVT-O would be to address the dyspareunia, and the placement of the retropubic sling, pubovaginal sling would be to address the stress incontinence. That would be my understanding of the intention of the physician, but I'm not him.

Q. Does a cadaveric pubovaginal sling present any risk of dyspareunia?

A. I think we talked earlier that the retropubic sling, which the pubovaginal sling is a type, does not traverse the levator ani, obturator internus, adductus, obturator externus, or exit on the groin, dramatically reducing the risk of dyspareunia.

Q. But there's still a risk of dyspareunia from

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the placement of a retropubic pubovaginal sling?

A. I think most surgeons will agree that vaginal sling surgery carries a risk, however small, of dyspareunia.

Q. Were there any complications in the June 14, 2012, surgery to -- with a plan to remove the TVT-O and then implanted the pubovaginal sling?

A. What do you mean by "complication"?

Q. Did anything go wrong?

A. Not from the operative report.

Q. Do you recall in the operative report that she tore the urethra during the surgery?

A. Yes. You're absolutely correct. Here is -- sling was noted to be sopped in close to the urethra, a tear in the urethra was noted while freeing up the sling, and it was closed with Chromic suture.

I just have to tell you that in terms of when you dictate an operative report, complications usually in the medical space refer to things that require subsequent multiple interventions, where you're unable to close a wound, for example, so you have to wake the patient up with a wound open.

Q. I see.

A. A complication from my point of view is

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something that transcends the actual surgical procedure. If you have a tear in the urethra, that's a known risk of explantation attempts, and you repair it intraoperatively, which this doctor did. So it would not be considered a complication from a medical practice point of view.

Q. So after the June 4, 2012, procedure, there are a number of office visits that you report in your chronology.

MR. TARASKA: David, I had mentioned to the Doc, but it's your call, that usually about every hour we take three or four minutes to get up and stretch around and come back, but if you're at a place where you want to keep going --

MR. THOMAS: Have we been going for an hour?

MR. TARASKA: Yeah.

MR. THOMAS: Let's just -- we'll do that. That's fine.

MR. TARASKA: If you don't mind.

MR. THOMAS: Not at all.

THE WITNESS: I know you guys like to ask a question before you go on break. Do you want to do that? It's up to you.

MR. TARASKA: I don't mean to interrupt your

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question.

THE WITNESS: I'm your man servant.

MR. THOMAS: Hardly, but I appreciate it. Short answer, yes.

(Recess from 10:09 a.m. until 10:15 a.m.)

BY MR. THOMAS:

Q. Doctor, obviously from the time that Dr. Windisch performed the second procedure on June 14, 2012, and did not remove the Gynecare TVT-O and in your opinion placed the pubovaginal sling, using cadaveric fascia, until November 30, 2015, when Ms. Ashbrook saw Dr. Reynolds and had another revision procedure, she has a number of office visits where she has certain complaints that you've recorded in your chronology; fair?

A. Yes.

Q. Are you able to determine the cause of the symptoms with which she presented --

A. Yes.

Q. -- at those interim periods?

What are they? What's the cause of her symptoms?

A. Well, for example, 3/21/2013 with Dr. Ballert, persistent daily stress and urge incontinence,

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persistent left groin pain and dyspareunia, groin pain and dyspareunia, definitely unquestionably attributable to the transverse TVT-O mesh that is still in place that you and I agreed was not explanted at that second surgery, daily stress incontinence, urge incontinence, probably related to some combination of the pubovaginal -- lack of function of the TVT-O sling and the pubovaginal sling, urinary urgency, severe constipation directly related to the fact that the TVT-O arms actually stab through the levator ani muscles causing spasm in the levator ani muscles. Women with spasm in levator ani are known to have severe constipation and difficulty emptying their bowels due to coarctation of the anorectal angle. Tender left pelvic muscles, palpable scar in the area of prior sling, tender left side, tender on right, all related and attributable to the transobturator sling.

Q. Is it your opinion that if the TVT-O had been removed, as Dr. Windisch stated in her operative report of 2012, that Ms. Ashbrook would not have experienced these symptoms?

A. Not correct.

Q. What is it -- what is your opinion?

A. Well, the transobturator sling passage, as we

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discussed, scars into the levator ani, obturator internus, and groin tissues. The act of removal of the insulting factor by itself does not make the symptoms go away. Many times those women can have improvement after removal plus additional therapy, but they never return to pristine preimplantation conditions.

Q. And that's based upon your clinical experience?

A. Clinical experience, absolutely correct.

Q. Is it based on any literature review?

A. Well, as we've talked earlier, I'm not here to talk to you about literature review. I'm talking about Ms. Ashbrook in the setting of my clinical experience with over -- well over 800 explantations of vaginal foreign bodies.

Q. Okay. So if the literature reported different experiences -- strike that.

So which of these symptoms -- strike that.

Looking at the December 6, 2012, office visit with Dr. Windisch, there's a report of dyspareunia. Do you see that?

A. Yes, sir.

Q. Is there a report of dyspareunia any -- strike that. I'm sorry. I made a mistake.

Is the significance of the placement of the

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pubovaginal sling in your opinion the fact that it was placed retropubically as opposed to through the transobturator?

A. What do you mean by "significance"?

Q. In terms of impact on Ms. Ashbrook and the problems that she experienced.

A. I'm not sure I understand the question.

Q. Can you place a pubovaginal sling through the transobturator? Is that done?

A. It's a definitional issue. The statement pubovaginal sling implies a retropubic placement.

Q. Thank you. Are there biologics or native tissue repairs -- strike that.

Can the Repliform sling be placed through the transobturator?

A. So by "can," is there a way to use a helical passer to place a Repliform?

Q. Good question. Good issue. Is it accepted standard of care to place a cadaveric sling through the transobturator?

A. I want to try to answer that question.

Q. Okay.

A. I recall there was a product by Bard that was a porcine sling, that I recall -- and, please, you know, I

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might have to be corrected on this -- had a transobturator placement component. I forget the name of it, but it was made by Bard Urological, and it was a porcine sling type material that had a retropubic placement, and it may have had helical passers for transobturator placement. I can't recall specifically.

Q. Okay. Let's go to your entry on March 21, 2013, which is the second opinion from Dr. Ballert. On exam, she shows tenderness at midurethral with palpable scarring. Are you able to determine whether the tenderness results from the TVT-O or the pubovaginal sling?

A. I'm able to determine.

Q. How?

A. Because the TVT-O is a midurethral sling. It anchors into the levator ani, obturator internus, adductor muscles and groin tissues. It is present at the midurethra. If there's palpable scarring, she's actually -- he or she is actually palpating the TVT-O sling. Tender levator muscles on left and on right go with the scarring of the TVT-O into the levator ani on left and right, leading to spasm, scarring, and pain.

Q. Anything about the urethral tear that occurred in the implant that would contribute to the scarring at

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the mid urethra?
A. So the midurethral tear was repaired in multiple layers using really fine chromic suture. That closure would happen at the level of the mucosa and the musculares. When the vaginal mucosa is closed over that, the likelihood of appreciating a scar there would be low.
Q. How low?
A. I think extremely low.
Q. So low that you shouldn't consider it as a source of scarring?
A. So it's much more likely that what she palpated in the tenderness of the mid urethra wasn't even the sling, transverse sling rather than the repair from the urethral tear. In addition to tender levator ani muscles, that would definitely not have been attributable to the midurethral tear.
Q. In March and May, Ms. Ashbrook is to see her gynecologist about a potential concurrent oophorectomy. Do you see that on your entry of May 21, 2013?
A. Yes.
Q. What's an oophorectomy?
A. Removal of an ovary.
Q. And based upon the symptoms that Dr. Ballert

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found in March and May of 2013 where there's a plan to see her gynecologist for a concurrent oophorectomy, why would that be a plan based on her symptoms?
A. Often when you go to see a gynecologist and they evaluate you, sometimes that evaluation is with imaging. If the imaging demonstrated an ovarian cyst of the right morphology, the suggestion would be to have that evaluated possibly for removal of the ovary. It would not necessarily be related to her urgent stress incontinence or levator ani pain or dyspareunia.
Q. But it is a potential source of her pain; correct?
A. I don't see that.
Q. Why not?
A. Because the ovary sits high up inside the pelvis, and the pain that this patient was experiencing was the levator ani. The ovary pain would probably be related to something like ovarian torsion, which was not described here. Looking at this from a gynecologist's eyes, the oophorectomy would probably be associated with an ovarian cyst, which was probably seen on imaging.
Q. And this is based on your review of the medical records?
A. This is based on my eyes looking at this as a

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gynecologist.
Q. Okay. Is it your review of the medical records in March and April of 20- -- excuse me -- March and May of 2013 that she's experiencing pain from the ovary, remaining ovary?
A. There is nothing in this record that I looked at, that I documented, that I transcribed, that tells me that the pain is from the ovary.
Q. But is she experiencing any pain from the ovary?
A. It was not described, and the likelihood of an ovary causing midurethral tenderness, levator muscle tenderness and pain at prior sling site is extremely low.
Q. So why would you remove an ovary if it's not causing any problems?
A. So as a gynecologist, women in certain age groups are not supposed to have cysts on the ovaries. So cysts on the ovaries are reserved for women that are premenopausal or still ovulating. If you have a woman who's postovulatory or postmenopausal with an ovarian cyst, that raises suspicion for a tumor. Then a gynecologist that's competent would recommend evaluation or removal of that ovary.

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Q. July 28, 2014, you note CT of the abdomen and pelvis, left flank pain, worsening left lower quadrant pain. Impression is moderate diverticulitis of descending colon. Is moderate diverticulitis of descending colon an explanation for left flank pain and worsening left lower quadrant pain in the opinion of the physician who made that note?
A. So left flank pain, that implies pain in the abdomen, back of the abdomen, lower quadrant pain implies pain in the abdomen, is consistent with diverticulitis, in my opinion.
Q. Okay. And is the same with the worsening left lower quadrant pain -- is that also consistent with diverticulitis of the descending colon?
A. So left lower quadrant pain could be caused by diverticulitis of the descending colon, yes.
Q. So you have no reason to disagree with that entry by the doctor?
A. I would make that same conclusion or raise that same concern.
Q. So the next -- strike that.
The next entry that I want to talk about is November 30, 2015, the procedure by Dr. Reynolds. And in this procedure Dr. Reynolds removed the

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transobturator sling, the TVT-O; correct? Page 14.
A. On page 15, I see the pathology report says vaginal mesh, two pieces. This leads me to conclude that he did remove a synthetic foreign body from underneath the urethra.
Q. And if you look on page 14, it says that he placed an autologous rectus fascial sling; correct?
A. Well, on page 14 it says he harvested it, but I'm going to agree with you that the goal of harvesting it was to actually place it. And here it is on page 15 he describes placing it.
Q. Was it placed retropubically?
A. Yes.
Q. Any indication that he removed the previous pubovaginal sling placed by Dr. Windisch?
A. I'm reading the report. I apologize.
There was no definitive statement that that previous sling was removed. However, you need to understand that biologic slings like the Repliform are notorious for actually being autolyzed by tissues. So you place them and you come back later and they're gone because they've been digested by the body. So he may not have had to remove that.
Q. Explain what that means, please, the autolyzed

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by the body.
A. The body produces enzymes that can digest tissues in the same way that it destroys bacteria from infection, for example. What some of us have realized is that placement of cadaveric materials like Repliform, Tutoplast and some of the other named cadaveric tissues is that you come back later, months later or years later, and you find that the previously placed material that was in there has been destroyed by the immune system, the body's immune system. Autolysis means digested.
Q. So why would you use a cadaveric sling to treat stress urinary incontinence?
A. I don't use them.
Q. Is that why?
A. I don't use them because I've not found them to be effective, and I also know from my own experience going back to look for these slings. And we've used them in the past in sacrocolpopexies, for example. And you go back, and they're just not there. They've been ingested. So I'm not surprised that the Tutoplast -- the Repliform sling was not even present when the doctor came in to do the autologous rectus fascial sling. Synthetic slings, however, tend to be around for long

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periods of time.
Q. They're supposed to be permanent?
A. That is the idea.
Q. March 25, 2016.
A. Page 15?
Q. That's correct. There's a CT scan and a left inguinal hernia; correct?
A. Page 16, yes.
Q. And you discount any role that this hernia plays in her left-sided groin pain; correct?
A. Well, I agree with Dr. Poulose, who is the general surgeon, who said that chronic pain is not due to hernia. It's more consistent with neuropathic pain. That's that doctor's version, and I would agree with that wholeheartedly. I would have arrived at that conclusion independently without even having read this.
Q. You typically would have required your own physical examination of the patient before reaching that conclusion, wouldn't you?
A. If this were my patient that came to see me clinically, I would evaluate the CT scan, look at her history of having a transobturator tape-type sling placed, in the setting of her history of groin pain, look at the CT scan and go, yeah, no, that's not it,

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it's the sling.
Q. Okay. Doctor, as I look through your chronology, your last complaint of dyspareunia is April 2013. Do you know whether that's true or not?
A. Well, not my complaint. This is her talking to her physical therapist. I'm just writing the notes down, writing the documentation down.
Q. What I'm trying to understand is, when you prepared this chronology, it was your goal to record all the symptoms that you related to the implant of the TVT-O and, at least from my review of your records, the last complaint of dyspareunia in your chronology of her medical records is April 2013.
A. And I'm glad you said it that way, because I'm basically documenting what was documented, and here the physical therapist says dyspareunia. Let me look. Left-sided groin pain, inguinal pain, mixed urinary incontinence, vaginal itching, burning on urination, abnormal uterine bleeding, urge incontinence, urge incontinence, worsening of incontinence, constipation, left groin pain. I'm just following through. Chronic pelvic pain is here on 4/5/2019. And so I don't document anything from the records specifically relating to dyspareunia, but that is not uncommon with patients

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as they reorder their symptoms based on what they perceive to be the severity and the most urgent.
Q. That's why you conduct your own interview and your own examination of the patient; correct?
A. Well, that's called a differential diagnosis. The patients -- and we see this quite common in medicine. If you think -- the patient comes to tell you about the thing that's most bothersome to them at the time. So, for example, a physical therapist would ask the question, are you having pain with intercourse? A general surgeon would not. Dr. Reynolds may not have asked that question because he or she was more focused on the urge incontinence. So the fact that it's not stated or documented does not mean that it wasn't present.
Q. Well, stated differently, the fact that it's not present doesn't mean that she had it.
Say it a different way, the fact that the complaint of dyspareunia does not appear after April 2013 -- let me ask it again.
Is there any evidence in the records, Doctor, that she had dyspareunia after April 2013?
A. The records do not state it, but the fact that the records do not state it may actually mean that the

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question was not asked.
Q. Okay.
A. And she did not volunteer it.
Q. Do you have an opinion whether she has dyspareunia today?
A. I can't answer that question.
Q. Because you don't have information from her to understand the answer?
A. Well, as you say in your business, asked and answered. This was not asked, and it was not answered --
Q. Okay.
A. -- by the patient.
Q. Okay. Let's go to page --
A. She does note chronic pelvic pain, however.
Q. But not dyspareunia?
A. Correct.
Q. And that's at her last visit on April 5, 2019; correct?
A. And if you would notice -- that's correct -- she's being followed at Vanderbilt for pelvic floor issues, which include pelvic pain and dyspareunia, which implies that this physician who is actually treating her -- when you say that, it means I'm treating her for

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the things that we're talking about here. Other people are treating her for the things like chronic pelvic pain issues, being followed at Vanderbilt.
Q. But there's nothing after April of 2013 that says she's been treated for dyspareunia.
A. So let me say again. So as a physician or a surgeon, when you treat a patient for a specific issue, as per Dr. Betsy Reynolds, who says wellness exam, reports five to six times daily chronic pelvic pain, overactive bladder, those are the things she's talked to me about that I'm willing to consider. When I say she's being followed someplace else for pelvic floor issues, which include chronic pelvic pain, dyspareunia and groin pain, that means that somebody else is taking care of that, and I'm not going to focus on it.
Q. Let's go to page 25 of your report, please. Down three-quarters of the way down, it says: "In my opinion, her chronic pelvic pain, groin pain, and dyspareunia occurred because of the scarring of the Gynecare TVT-Obturator mesh into the anterior vaginal wall and pelvic floor, obturator, and groin issues, followed by postimplantation contraction of the TVT-Obturator mesh, which placed traction on the pelvic floor, obturator, groin muscles, and tissues."

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What's the evidence for this statement? What's the evidence for the statement that the mesh had scarred into the pelvic floor or side wall muscles?
A. Anatomic and physiologic. Everybody agrees that healing occurs via scarring. Everyone agrees that the meshes and the polypropylene materials for TVT work because of tissue ingrowth. There's no discussion about that. Everyone agrees that healing involves contraction. And so by extension, the mesh material is passed through the levator ani, the obturator internus, the adductors and the groin tissues. It scars into place in those tissues. In the healing process, the mesh contracts. With such contraction, it pulls anatomically on the levator ani, obturator internus and adductor muscles and the groin tissues. With such contraction, there's spasm of the levator ani, the obturator internus and the adductor muscles. With spasm, there is tenderness and pain with attempts of penetration and with movement.
Q. You agree that none of the operative reports indicate any evidence that the mesh had scarred into the pelvic floor or side wall muscles?
A. The obturator reports -- the obturator -- the operative reports would not have mentioned that, but the

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scarring is implied by virtue of the placement of the mesh, the knowledge that tissue ingrowth is critical to the functioning of these meshes, the fact of this contracture after healing, and scarring. That's an anatomic and physiologic fact set.

Q. So is it your opinion that mesh scars into the pelvic floor or side wall muscles of every person who receives a TVT-Obturator?

A. The whole selling point for the meshes that are placed is that they work by tissue ingrowth. There's no taping. There was no suturing of TVT meshes for the reason that it scars into place into tissues. That's how it works, so that's a fact.

Q. So why does not everybody who received a TVT-O have chronic pelvic pain, groin pain, dyspareunia? If it occurs in everybody, why didn't --

A. Scarring occurs in everyone. The different humans -- people have different heights. People have different shaped noses. They have different shoulders. Some are broad. Some are narrow. Different humans react differently to clinical settings. Pain levels are different in people. But I tell you that it's a fact that the TVT-O -- and Johnson & Johnson knows this. Every mesh manufacturer knows this. They work by

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scarring into place. And, in fact, if you look at the IFU, the IFU says don't put sutures in this mesh, because it scars into place.

Q. So why does it happen in Ms. Ashbrook and not other people who have good results or outcomes with the TVT-O?

A. What do you mean? We don't know that it doesn't happen in those people.

Q. Why do -- why does Ms. Ashbrook have chronic pelvic pain, groin pain and dyspareunia of the TVT-O when others do not?

A. How do we know that others do not?

Q. Randomized clinical trials.

A. Uh-huh.

Q. Do you know whether there have been any randomized clinical trials done with the TVT-O?

A. I'm told and I've read from your reports that there is lots of them. I'm telling you again anatomically that the fact is the TVT-O is supposed to work by tissue ingrowth. That means scarring. You know and Ethicon knows and every doctor knows that healing happens by contracture. If I scar into a muscle and I contract, then that will cause pain.

Q. But you've not reviewed the randomized clinical

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trials?

A. I'm here as a case-specific expert talking about Ms. Ashbrook and her examination and her symptoms.

Q. So the answer is no, you have not reviewed the randomized clinical trials?

A. I can't answer that question because I'm here as a case-specific expert. I'm not a general expert.

Q. Are you familiar with what is known as a Cochrane Review?

A. I've used that system.

Q. What is a Cochrane Review?

A. It is an attempt by people who consider themselves to be qualified to review clinical data to review the -- what they consider to be the universe of data and trials to indicate whether a process or a technique or a procedure has clinical support or not, clinical trial support or not.

Q. And you've used Cochrane Reviews in your practice?

A. Generally speaking as part of my CME and learning, reference is made to Cochrane Reviews and other trials.

Q. Do you find Cochrane Reviews to be authoritative?

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A. What do you mean by "authoritative"?

Q. Useful in your field to help you make decisions about care and treatment of patients.

MR. TARASKA: Form objection.

THE WITNESS: Yeah, it's -- they're -- they highlight studies and trials related to specific areas, and I have learned to go and look at what they've reported. And when I have a true question, I would go back to the source data.

BY MR. THOMAS:

Q. Have you reviewed the Cochrane Reviews on midurethral slings?

A. I can't talk about that for this, because I'm a case-specific expert.

Q. Can you answer the question? You won't answer the question or you can't answer the question?

A. What is the question?

Q. Have you -- have you reviewed any Cochrane Reviews on midurethral slings?

A. I have not reviewed Cochrane Reviews on midurethral slings for the purpose of this case.

Q. Are you familiar with the Cochrane Reviews on midurethral slings?

A. I'm familiar that such reviews exist as part of

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my background.
Q. Have you ever studied the Cochrane Reviews for midurethral slings comparing retropubic slings to TVT-O slings?
A. Not specifically for this case.
Q. How about any time?
A. Over the course of my multitude of years in FPMRS, I'm sure that I have.
Q. Do you have any recollection of what the Cochrane Reviews show comparing retropubic approach as compare to the obturator approach?
A. I have a recollection that the retropubic approach is substantially different from the transobturator approach. I have a recollection that they're lumped together as the general topic of midurethral slings of which the majority of those studies refer to retropubic slings, which is not the sling that's used in Ms. Ashbrook. The conclusions from retropubic slings were applied to midurethral slings as a group, when, in fact, the majority of the data supports retropubic slings, not transobturator slings.
Q. Is that your understanding of the Cochrane Reviews?
A. That is my understanding of the Cochrane

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Review. The bulk of the data relates to retropubic slings, and was aggregated and said to apply to the term midurethral slings, of which there are two varieties, substantially different trajectories. You can't apply data from a retropubic sling to a transobturator sling, because they're different.
Q. Page 26 of your expert report. Right in the middle of the page, you say: "Iretta Ashbrook's persistent groin pain, pelvic pain, chronic dyspareunia, and constipation would not have occurred with a native tissue repair like the Burch colposuspension or a retropubic sling."
It is fair that pelvic pain is a risk factor for the Burch or the retropubic sling; correct?
A. So pelvic pain is a risk factor for gynecologic surgery. The size of the pelvic pain and the amount and the likelihood and the extent are substantially different depending on which surgery you do. I can do a surgery on the vagina that overtightens the vaginal caliber that would make it 100 percent likely that she has dyspareunia and pelvic pain. I can do that same surgery in a more -- in a less vigorous fashion that would make the risk of her having chronic pelvic pain substantially less.

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Q. So is it your testimony that groin pain, pelvic pain and chronic dyspareunia and constipation are risk factors with any gynecological surgery, but they are less with a Burch or a retropubic sling than with a TVT-O?
A. I didn't say that.
Q. I'm asking you that.
A. That's not what I'm saying.
Q. Okay. Are groin pain, pelvic pain, chronic dyspareunia, and constipation risks of the Burch colposuspension?
A. Highly unlikely.
Q. Based on your clinical experience or literature?
A. Clinical experience, anatomy, and physiology.
Q. But not a review of the literature?
A. Clinical experience, anatomy and physiology.
Q. All right. And is it your opinion that persistent groin pain, chronic dyspareunia, and constipation are not risk factors with retropubic sling or that they're less?
A. So you're talking about the outcome being a risk factor? Please clarify your question.
Q. Do you have a risk -- does the retropubic sling

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present a risk of groin pain, pelvic pain, chronic dyspareunia and constipation?
A. Extremely low.
Q. And when you say "extremely low," how does it compare to the risk for pelvic pain as presented by the TVT-O?
A. We talked earlier and I reiterate again that the TVT-O trajectory courses through the levator ani, the obturator internus, the obturator externus and the adductors as well as the groin tissues. Those particular tissues, when the TVT-O scars into place and contracts, causes spasm in the obturator internus and levator ani muscles and the groin tissues, leading to an extremely high risk of pain in those tissues. The pain is not transient. It is long term.
Q. Is the risk of chronic dyspareunia less for a retropubic sling than it is for a sling placed through the obturator?
A. I think if you look at the anatomy, you can't help but agree that the likelihood of causing chronic dyspareunia from a retropubic sling appropriately placed is a different profile than compared to a TVT-O.
Q. Do you know what the scientific studies of the literature say on the topic?

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A. I'm not here to talk about scientific studies.
Q. Well, do you know?
A. The setting -- I understand that, just as a background matter, groin pain tends to be higher in transobturator.
Q. I'm talking about chronic dyspareunia.
A. Chronic dyspareunia, I don't know that I know the answer to that question.
Q. You agree that any current stress urinary incontinence Ms. Ashbrook suffers is a result of the failure of the autologous fascial sling, not the TVT?
MR. TARASKA: Could you say that again? I lost that.
BY MR. THOMAS:
Q. Do you agree that any current stress urinary incontinence Ms. Ashbrook has is the result of a failure of the autologous fascial sling, not the TVT-O?
A. I do not agree.
Q. Why is that?
A. Because the initial persistence of her stress incontinence came after the TVT-O procedure. Subsequent procedures, the pubovaginal sling with the Repliform, and then the autologous fascial slings were attempts to correct that persistent stress incontinence.

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Q. Recurrence is a known risk of any treatment for stress urinary incontinence, isn't it?
A. Recurrence of the stress incontinence, yes.
Q. Do you agree that rates of postoperative void dysfunction, urgency and retention is lower with the TVT-O than with an autologous sling or the Burch colposuspension?
A. I would agree with the autologous sling. I'm not sure about the Burch colposuspension.
Q. Do you have any literature support for your suggestion or your opinion that the TVT-O causes problems with bowel movements or constipation?
A. I have anatomic reasons for telling you why that is in the setting of clinical experience with many hundreds of patients who present with TVT-O type insertions that come in with chronic constipation that they did not have before.
Q. Do you have any medical literature, published studies, published papers which support your opinion that TVT-O causes problems with bowel movements or constipation?
A. You've asked a number of times about published studies. In order to have a published study that's validated, the published study has to be asking the

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right questions. So the question of did you have constipation before, are you examined and validated to have no constipation, have the procedure intervention and then evaluated constipation specifically, I've not seen a piece of literature that specifically targets constipation as a primary outcome related to the placement of the TVT-O. So the fact there's no data on or no literature can also mean that the question has not been adequately asked or vetted.
Q. What would you prescribe to address her current condition? How would you treat her today?
A. Well, I think we talked about -- well, let me see if we talked about that.
Q. You told me before that her outcome was uncertain. You've told me -- you've told me a minute ago that you thought it was unlikely that she would recover. I don't think we've talked about what you would try to treat, how you would try to treat Ms. Ashbrook.
A. So Ms. Ashbrook's chronic pelvic pain, groin pain, and pain with intercourse, she's not had a course of vaginal estrogen, which would have been the first thing that I would try. It makes her vaginal atrophy an unlikely cause of her dyspareunia. It's more likely

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than not that her pain are due to the vaginal wall scarring from the TVT-Obturator and the subsequent surgeries to remove the expanding mesh.
Ms. Ashbrook very likely has remaining arms of the TVT-Obturator sling embedded in her groin, because these would not removed by her explanting surgeon. The attempt that I would make would be to locate those arms in the groin and explant those via groin dissection. However, despite that explantation, I would hope that there would be a likelihood of improvement. However, I believe the injury caused by the scarring due to the placement trajectory is more likely than not to cause permanent injury to her.
Q. How do you know the extent of the mesh that is left in her body?
A. How do I know?
Q. Uh-huh.
A. So the mesh placement involves passing through the levator ani, the obturator internus, the adductors, and the groin tissues. I know and we know from the placement that the arms of the mesh occur in the vagina and also in the groin tissues. I know from the operative report that the doctor described dissecting the mesh to the obturator internus, mostly to the pelvic

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side wall specifically, which says that there are remnants of the mesh arms in lateral to the obturator internus muscles and in the groin tissues. They remain, and they're the cause of her groin pain.
Q. And how do you know that they are the cause of her groin pain?
A. Because they pass through the adductor muscles and the groin tissues probably -- actually scarred into place, which exacerbate -- which causes her groin pain. Foreign body in the groin causes groin pain.
Q. And is it your opinion that there's no other reasonable explanation for the cause of her groin pain?
A. In my field, there's a methodology called Bayesian analysis, B-a-y-e-s-i-a-n, which starts with a prior probability of something being the cause of a problem. She has an insult and a foreign body embedded in her groins, which cause pain. She is having the pain consistent with that foreign body embedded in her groins. Therefore, that is the source of her pain. It is not from an injury. It is not from an inconsequential hernia. It is related to the foreign body that's embedded therein.
Q. That's based on your review of the medical records?

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A. Based on my review of the medical records and the fact that the trajectory of the TVT-O is very clear.
(Hoyte Exhibit No. 5 was marked for identification.)
BY MR. THOMAS:
Q. You worked at Brigham & Williams -- excuse me. You worked at Brigham & --
A. Brigham & Women's.
Q. I've been there. I know exactly where it is. Doctor, you've worked at Brigham & Women's Hospital before; correct?
A. Correct.
Q. And did you work with a Dr. Rajan, R-a-j-a-n?
A. Sujatha Rajan, yes.
Q. And did you work with a Dr. Shah, S-h-a-h?
A. I have.
Q. I'm going to hand you what I've marked as Deposition Exhibit No. 5. Deposition Exhibit No. 5 is an abstract of an article published in the International Urogynecologic Journal in 2006. Do you see that?
A. I see that.
MR. TARASKA: Okay. I'm going to ask for a short break so he can read the entire document that you gave him.

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MR. THOMAS: He doesn't need to yet. I mean, if he wants to read it, he's certain to, but I --
MR. TARASKA: I want him to read it before he answers any questions about it, so --
MR. THOMAS: I don't --
MR. TARASKA: Well, you're going to ask him --
MR. THOMAS: You're -- with all due respect, I don't think it's right to do so unless he asks to do it, and I'm disappointed that you interjected yourself in the deposition, because I don't think it's appropriate.
MR. TARASKA: Okay. Here in Florida, if you hand the doctor a document, which is a piece of literature, he has the right to stop and review the entire document before he answers any questions on it. I would like him to do that at this point. I think that's fair. I don't think it's fair to ask him questions on something he hasn't read, so that he has an opportunity to understand the context of your question. So I am asking that you give him that opportunity now.
MR. THOMAS: I will certainly do that, but I will note that he is an author on this study.
MR. TARASKA: That's fine. That's fine.

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THE WITNESS: So do I have time?
MR. TARASKA: Yes. Take your time to read it.
MR. THOMAS: Take your time.
MR. TARASKA: Which one is it, David? Is it 249 or 250? 250; right?
MR. THOMAS: Yes.
MR. TARASKA: Thanks.
(Recess from 11:00 a.m. until 11:02 a.m.)
BY MR. THOMAS:
Q. Doctor, directing your attention to Exhibit No. 5, in addition to Dr. Rajan and Dr. Shah, it shows L. Hoyte. Is that you?
A. That would be me.
Q. Okay. And this is an abstract in 2006. When I looked at your CV, it's not on your CV.
A. That is correct.
Q. Why not?
A. I totally didn't remember it.
Q. Okay. Do you still adopt this work that you did and published in 2006?
A. The work is published. It has my name on it. I have to stand by it.
Q. Okay.
A. I'm not trying to hide anything, but I just

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didn't have it included.
Q. Okay.
A. Good of you to find it.
Q. Under objective, the objective of the work that you did with these other folks was to evaluate the efficacy of the transobturator (TOT) sling for recurrent stress urinary incontinence.
A. Correct.
Q. And TVT-O is a transobturator sling; correct?
A. Correct.
Q. And what was your role in this study?
A. I was on the faculty at Brigham & Women's Hospital in the urogynecology group with Neeraj Kohli, who's an author under -- senior author of that.
Q. What role did you play in the study?
A. I probably was an advisor to the study.
Q. Do you remember?
A. I don't.
Q. Okay. And under materials and methods, the abstract reports that a retrospective multicenter study of consecutive TOT slings performed for recurrent stress incontinence over a 48-month period was performed. Patients were considered for this study if they underwent a TOT sling following prior antiincontinence

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procedure.
How many patients were in the study? If you look on the next page, I think it says 47.
A. I thought it was 48, but let me see. 47 patients were included.
Q. Okay. And you've now had a chance to review this study. Does it refresh your recollection about what happened?
A. It does not. It was in 2006.
Q. Okay. Of the 47 patients, right in the middle they report what happened in terms of intraoperative issues and postoperative issues. Do you see that? Right in the middle. "There were no intraoperative complications."
A. Okay. I see that.
Q. Which means what? There were no intraoperative complications?
A. That's the problem. I don't know what that means.
Q. Okay.
A. No one knows what that means.
Q. Okay. Postoperatively one patient had sling erosion and two patients had incomplete bladder emptying. Urge incontinence was reported by 34 patients

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(72 percent) preoperatively, by 18 (38 percent) postoperatively. Four patients (8 1/2 percent) developed de novo urge incontinence symptoms.
What's the purpose of reporting that information in an abstract like this?
A. So the purpose of reporting that -- first, de novo urge incontinence symptoms is not defined. We don't know what the parameters of that means. We don't have a definition of what it meant before or after the fact. The purpose would be to say -- an attempt to say by the authors that whatever was defined as urge incontinence is an occurrence. They're attempting, I think, here to say -- if you read it on face value, it says urge incontinence existed preoperatively, but half of them essentially didn't have it postoperatively. That's an attempt to say, I believe, that the TVT, quote, cured urge -- TOT cured urge incontinence. But there's no supporting data to tell me in the -- I couldn't repeat this experiment just from reading this here.
Q. Well, it's an abstract. It's not a full study; correct?
A. Well, abstract is preliminary data for work that you would undertake.

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Q. So the conclusion that's reached in the abstract that's published in the International Urogynecologic Journal in 2006 says: "The transobturator midurethral sling appears to be an effective and safe option for the treatment of recurrent stress urinary incontinence" -- "stress incontinence in women." Let me start over again. I read that wrong.
Conclusion reads: "The transobturator midurethral sling appears to be an effective and safe option for the treatment of recurrent stress incontinence in women with urethral hypermobility and normal urethral function."
Do you agree with that statement?
A. I see that that statement is made, but one of the things you might want to notice is that the objective was to evaluate the efficacy for recurrent stress incontinence, and the conclusion talks about safety.
Q. Well, does it? It says -- I don't mean to stop you there, but it says, the transobturator midurethral sling appears to be an effective -- that's efficacy, isn't it?
A. Yes. But it was not defined.
Q. Okay. Do you disagree with that statement with

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your name on this abstract?
A. My name's on the abstract, but I'm telling you about the nature of an abstract. The conclusions are not supported by what's -- it's not supported. It's not set up to arrive at a conclusion.
Q. Okay.
A. So we can say it's appears to be effective. Appears. So as far as I can tell looking at this from a bird's-eye view, I put in 47 TOTs -- somebody put in 47 TOTs, because I didn't do any surgeries with this procedure. This is a retrospective study of surgeries performed by Drs. Miklos and Kohli. And in retrospect, going back, this is not a prospective trial. It's not Level 1 data. It's probably Level 3 or 4 data. And you're telling me that it's an effective and safe option for the treatment. It's an abstract. You can't -- I don't know what else to say.
Q. Well, you published it, didn't you?
A. It's an abstract, so...
Q. You didn't say you can't rely on it.
A. We submitted this. They submitted this with -- and I was a party to it, but it is an abstract. It's not a prospective. It's Level 4 data.
Q. As a matter of fact, you say at the end,

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"Larger prospective and comparison studies are needed in order to confirm these preliminary results."
A. Confirm, which means these results are extremely preliminary, and none of these results talk about how they arrive at the parameters for saying that it's effective. Effective means 30 percent cure rate. Effective means 40 percent cure rate. Safe means -- I don't know what safe means in the setting of 48-month data.
Q. And do you know the extent to which larger prospective and comparison studies have been done in order to confirm these results?
A. I have not. It's a good pickup. I have to add this to my CV, and I must apologize to everybody else. I've told erroneously that I've not had a study in my name.
Q. And so do you agree with this statement: The midurethral sling is the most studied surgery to treat stress urinary incontinence and there have been over 2,000 articles published about it?
A. So when you lump retropubic slings with transobturator slings and call them midurethral slings inappropriately, yes, there's 2,000 studies. Nobody's going to argue with that. The bulk of those studies

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relate to the retropubic sling, which is not the sling that's the subject of Ms. Ashbrook.
Q. I see. So do you know of any studies that have compared the obturator approach versus the retropubic approach?
A. Those studies exist. I know them. I can't quote them off the top of my head.
Q. You've not considered those in your report, though? Those are not contained in your report?
A. Remember, I'm a case specific. I did not go to the literature here.
Q. Okay.
A. I think if we were to do that and review all of the 2,000 studies that Dr. Kenton, for example, your expert, referenced -- we can review each one of those individually and see what category they fall into and what the impact is on Ms. Ashbrook's outcome, but absent that, I don't think we're in a position to discuss this.
MR. THOMAS: Doctor, that's all the questions I have.
MR. TARASKA: Thank you. I have a couple.
CROSS-EXAMINATION
BY MR. TARASKA:
Q. Doctor, let me refer back to this abstract that

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was discussed with you by Mr. Thomas. There's a sentence here on the second page that says: "Mean duration of follow-up was 30 weeks. The range was 4 to 90."
What does that mean, "mean duration of follow-up"?
A. So mean is a fancy word for average, generally speaking, so -- which means 50 percent of the patients were followed for less than 30 weeks and 50 percent were more. If you average the length of follow-up, you'll see that the range it's as few of four weeks of follow-up and as long as 90 weeks, which if you did the math, that works out to -- I don't know in months. On the average, patients were followed for 30 weeks.
Q. So does this mean that these 47 patients, after they had this operation with the TVT-O, were only followed for that period of time, at least as reported in this study?
A. Well, it wasn't a TVT-O. It was a TOT. And I apologize. I'm not sure -- but it's the trajectory that we're talking about. Some patients were followed for as few as four weeks. Some were followed for as long as 90 weeks. We don't even know the distribution of whether they were 90 percent of them were followed for four

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weeks and 1 percent for 90 weeks or 90 percent for 90 weeks and 1 percent -- I just don't know.
Q. So what happened to these patients at two years out or three years out?
A. Unspecified.
Q. Am I correct that some of the problems that can occur with this particular type of implantation can be seen years out as the mesh erodes and causes problems with the muscles through which it has been implanted?
MR. THOMAS: Object to form of the question.
THE WITNESS: I think in Ms. Ashbrook's case the implantation was in 2010, and the beginnings of her issues with explantation began in 2012. I think many years can go by before patients are able to correlate their symptoms or the complaints with the fact that it may be -- it may be the implantation that's the problem.
BY MR. TARASKA:
Q. Let me rephrase that question. I had a form objection.
Do patients -- do some patients who have had this implantation -- let me strike that.
Let me rephrase it this way: Am I correct that the mean follow-up on this study was 30 weeks; is that

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correct?
A. On average patients were followed for 30 weeks.
Q. Some as few as four weeks?
A. Correct.
Q. Some as long as 90 weeks?
A. That is correct.
Q. All right. Am I --
A. 90 weeks is about 11 months.
Q. No. Yeah, it's a little longer than that. 52 weeks in a year.
A. Two years, three years. You can tell I'm a doctor and not a mathematician. Two years.
Q. So what was the outcome of these patients two years, three years, four years in this cohort study after the implantation of this device?
A. No one knows from this abstract.
Q. Okay. And do some patients actually begin to exhibit at least and report the symptomatology, such as Mrs. Ashbrook has, years after the implantation?
A. Yes.
Q. Well, she would be outside this range, wouldn't she?
A. Let's see. So the professor -- the counsel corrected me in that 90 weeks is just under two years.

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Ms. Ashbrook's second surgery occurred about -- so 10/29/2010 to 6/14/2012 is about two years.
Q. Okay. All right. How many surgeries have you performed, do you believe, in your career to try and explant this type of material from human beings?
MR. THOMAS: Object to the form of the question.
THE WITNESS: Answer?
BY MR. TARASKA:
Q. Yes, sir.
A. Okay. I stopped counting at over 800 transvaginal mesh implantations. That was several years prior.
Q. And as you discussed with Mr. Thomas today the basis for your opinions, were you taking into account these hundreds of opportunities that you have had to actually examine and view human beings who have had implantations?
MR. THOMAS: Object to the form of the question.
THE WITNESS: Women with transvaginal mesh helped me to form my opinions, yes.
BY MR. TARASKA:
Q. Since 2006 when this abstract was published,

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how many human beings do you think you've had the opportunity to actually work with and try to explant materials such as occurred with Mrs. Ashbrook?
MR. THOMAS: Object to the form of the question.
THE WITNESS: Well over 800.
MR. TARASKA: Can you tell me what was wrong with the form of that question?
MR. THOMAS: Sure. Material in Ms. Ashbrook covers all kinds of mesh for all kind of reasons.
MR. TARASKA: Good question.
BY MR. TARASKA:
Q. Let me rephrase that. Since 2006, how many women have you had the opportunity to examine and work with in an attempt to explant the type of material that was implanted in Mrs. Ashbrook that was done with the TVT-O sling that was put into her?
A. Okay. So I can answer that explantation of transvaginal mesh products are well over 800. I do not have an exact breakdown of transobturator sling type explantations. However, they are in the hundreds.
Q. Thank you, sir. There was some discussion early on in the discussion of polypropylene -- help me with the pronunciation --

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A. Polypropylene.
Q. -- polypropylene slings. Does a polypropylene sling, in your opinion and your experience, create a problem with the type of implantation that occurs in a TVT-O implantation?
A. So I think what I said is that polypropylene as a material has been used as an implant both as sutures and as synthetic mesh materials in humans for quite some time. Polypropylene retropubic slings have been used in women to address stress urinary incontinence. When placed retropubically, they seem to perform and behave better than when they're placed in a side-to-side or transobturator-type configuration. In the case of Ms. Ashbrook, she has a side-to-side transobturator configuration of a polypropylene sling, and they are a different animal, in my opinion, to retropubic polypropylene slings.
Q. Why, anatomically and physiologically, does that occur?
A. The retropubic placement of the polypropylene sling goes through the vagina, it goes through paraurethral tissues, it goes up through the space of Retzius, which is a potential space between the pubic bones and the bladder, and it exits out through the

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rectus tendon, the anterior abdominal wall subcutaneous tissues and hides under the anterior abdominal wall skin. There's no transgression into skeletal muscle for this procedure when done appropriately.
In the transobturator case, the transobturator version of the sling lies underneath the vaginal mucosa for the distance from the mid urethra to the pelvic side wall. It goes into the levator ani, the obturator internus, obturator externus, adductor muscles and groin tissues. It perforates and scars into place in multiple muscle systems that critically affect function like sexual function, defecatory function, movement, for example, getting in and out of a car, and body stabilization. It is a different trajectory.
Q. What is it about the use of polypropylene in the type of implantation that she had that can cause additional problems?
A. I think the polypropylene in of itself is designed to work by scarring and tissue ingrowth. In the space of Retzius there's less critical tissues that are ingrown to compared to the transobturator version in which case there's, as I said, levator ani, obturator internus, obturator externus, abductor muscles and groin tissues. There's much more scarring into tissues that

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have critical function.
Q. You were asked about interviewing and evaluating this woman, Mrs. Ashbrook. Do you believe that you are able to render appropriate medical opinions within a reasonable degree of medical certainty as you have today without interviewing her or evaluating her?
A. Yes. Based on the extensive documentation that was provided by her board-certified physicians and surgeons, I have the information I need in order to render an opinion more likely than not.
Q. You were asked questions about the implanting surgeons and the explanting surgeons. Do you have any criticisms of these surgeons?
A. I do not insofar as their surgical technique and judgment is concerned. I do not.
Q. Okay, sir. And you were asked about one of the surgeons, Windisch, I believe, whether or not he had actually explanted the mesh material. Do you recall those questions?
A. Yes.
Q. All right. From your own experience, sir, can you describe for us the difficulty in explanting mesh material once it has been implanted for this period of time as it was with Mrs. Ashbrook?

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MR. THOMAS: Object to form of the question.
MR. TARASKA: Can you tell me what's wrong with the form?
MR. THOMAS: Sure. It's a general question. This is case-specific. Unless he has an opinion of the difficulty of removing Ms. Ashbrook's mesh, which he can't because he wasn't there, his opinion is not appropriate.
MR. TARASKA: Okay. I'm going to let the question stand, and then I'll rephrase for follow-up.
BY MR. TARASKA:
Q. Go ahead, sir.
A. Okay. So in my abundant experience explanting transobturator-type slings, side-to-side placed slings, I note that they're extremely difficult to locate intraoperatively. They're described as midurethral slings. However, I've seen placements as distal as within .5 centimeters of the urethral meatus all the way up to the bladder neck. Techniques for highlighting or causing the sling to show itself, very varied. They're unpredictable. Sometimes you can go in and attempt to locate the sling material, but they're very, very difficult to locate.

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Q. Do you have an opinion, sir, based on reasonable medical probability, as to why it was difficult to extract or explant the mesh material in Mrs. Ashbrook?
MR. THOMAS: Same objection.
BY MR. TARASKA:
Q. And I'm talking about the TVT-O sling material that was implanted in her.
MR. THOMAS: Same objection.
THE WITNESS: As I said before, they're difficult to locate, in my experience. It takes quite a lot of experience, judgment to attempt to locate these transobturator slings. And there has been no formal educational process that I know of that was designed to help surgeons locate and explant transobturator slings.
BY MR. TARASKA:
Q. What is it about the TVT-O mesh material that was put into Mrs. Ashbrook and the manner in which it was put in that makes it so difficult to extract?
A. Well, first, it's difficult to locate. I think having located it, then it's difficult to extract from the imbedding in the groin and pelvic side wall tissues because of the path, the blind placement path going

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after that. The sling arms that are laterally placed involves dissection, which necessarily has to be blind and puts tissues at risk, nerves and blood vessels at risk for injury, permanent injury. So it's difficult to locate, and it's difficult to extract in its most lateral aspects.
MR. TARASKA: Those are the only questions I have. Thank you, sir.
REDIRECT-EXAMINATION
BY MR. THOMAS:
Q. I have a couple follow-up questions for you, Doctor. Did I understand you correctly to say that you've explanted hundreds of Ethicon TVT-Os?
A. That's not what I said.
Q. I didn't think you did. What did you say?
A. I said I've explanted over 800 transvaginal mesh products. I lost count about three or four years ago. I don't have an exact number of how many of those are transobturator-placed devices. However, that number is in the hundreds.
Q. Okay. And my question is: How many of those are Ethicon TVT-Os?
A. Difficult to know.
Q. Do you have any idea?

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A. Difficult to know.
Q. Are you able, when you explant meshes placed in the obturator, to determine the kind of mesh that it is, the manufacturer of the mesh?
A. Yes.
Q. Do you make a note in your medical records of the kind of mesh that it is?
A. So there was one particular manufacturer, who is not Ethicon, whose name I won't call, that has a very distinctive appearance to their mesh. When I extract from that manufacturer, it's very clear who that is.
Q. Who is that?
A. It's not Ethicon. It's Coloplast.
Q. Okay.
A. Other meshes sometimes are differentiated on their color. Some are blue. Some are white. But just looking at the appearance of the mesh, one is not able to tell who manufactured it.
Q. Okay.
A. And one does not always have access to the operative reports. In cases where I do have access to the operative report, I've seen a number of them that said Johnson & Johnson or Ethicon, but I don't have a number. I don't keep track of those.

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Q. Do you have any idea how many there are, how many Ethicon TVT-O meshes you've explanted?
A. I couldn't say because I don't have that documentation.
Q. Okay. Would your medical records that you maintain for the patients in which you've explanted these meshes identify the mesh that you explanted?
A. If they have their operative reports with them, they would. My operative reports do not, as a matter of course, state what manufacturer I think it is.
Q. Is there any way that I can determine from a review of medical records in your possession whether or how many TVT-O meshes you explanted for woman over the years?
A. I don't know how you would be able to do that unless you go -- went after the implanting operative reports.
Q. And is there any way that you can tell from your review of your medical records whether or how many Ethicon TVT-O meshes you've explanted from women?
A. As I've said before, I don't keep track of that in the medical records. The only time I would have that awareness is if I had cause to review the operative report of the implantation.

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Q. And if you had cause to review the operative report from the implantation, is that included in your medical records?
A. It is the -- the review of the operative report sometimes is. The product is not.
Q. The name of the product is not?
A. The manufacturer product name is not.
Q. Okay. So neither you nor I have any way of going back through the medical records that you have to determine which of your patients have had a TVT-O removed; is that fair?
A. Unless the operative implanting report is also present.
Q. And you don't know whether you have that or not --
A. I don't.
Q. -- until you look at it?
A. I don't routinely get them.
Q. Okay. And if I were to ask you to produce for me patient files for every patient where you've removed a TVT-O from a patient, could you do that?
A. So you say to me give me a list of all the TVT-O patients that you've operated on to remove their product?

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Q. Yes.
A. I don't know how I would do that.
Q. Okay. So, likewise, you couldn't give me the files or the operative notes or any information that you have about those patients that I can go in and look at the individual circumstances of each of those mesh removals; is that fair?
A. So I think to do that you would have to go to Judge Goodwin and subpoena every single explant that I've done and then go to their records and subpoena the implantation and then look at them that way. I think that's highly unlikely.
Q. Highly unlikely because you wouldn't give them to me or I wouldn't be able to figure it out because Judge Goodwin wouldn't allow it?
A. I don't see Judge Goodwin allowing that, but if he said do it, then we can do it. You and I could spend 120 hours and do that.
Q. And we could figure out whether TVT-Os were explanted? I thought you just told me we couldn't.
A. So we would get my operative reports. We would get the implanting operative reports, and we would sit down and review all of them together with the information on the stickers for the product that was put

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in. And we can go through and pick out Altis, Supris, Aris, Prolift, and all the other products. We can do that. That would be the rest of our lives.
Q. But as I understand it, there's no way to -- I thought you told me before you couldn't tell whether they were --
A. From my reports I can't tell. If you were determined to do it and you had the right amount of time, we could get a subpoena that would go and find all of their implanting reports, and we can review them and see what was implanted.
Q. And my question is simply this: From your records, the records that you maintain for the patients where you've explanted these meshes, neither you --
A. We can't do that.
Q. We can't figure out what mesh it was?
A. There's not enough information. Generally speaking, unless in that report there is an implanter's report which says, "And I implanted a TVT-O from Johnson & Johnson" or "I implanted a TVT-O Abbrevo," so forth. Some of those records exist. I don't know which ones there are.
MR. THOMAS: Okay. That's all the questions I have. Thank you.

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MR. TARASKA: Thanks. That's all I have too.
(Whereupon, the deposition concluded at 11:32 a.m.)

CERTIFICATE

I, JOAN L. PITT, Registered Merit Reporter, Certified Realtime Reporter, and Florida Professional Reporter, do hereby certify that, pursuant to notice, the deposition of LENNOX HOYTE, MD, was duly taken on October 22, 2019, at 9:16 a.m., before me.

The said LENNOX HOYTE, MD, was duly sworn by me according to law to tell the truth, the whole truth, and nothing but the truth, and thereupon did testify as set forth in the above transcript of testimony. The testimony was taken down stenographically by me. I do further certify that the above deposition is full, complete, and a true record of all the testimony given by the said witness.

_____

JOAN L. PITT, RMR, CRR, FPR

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby acknowledge that I have read the foregoing pages, 1 - 106, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____ _____

LENNOX HOYTE, MD DATE

Subscribed and sworn to before me this

____ day of _____, 20___.

My Commission expires: _____

_____

Notary Public

LAWYER'S NOTES

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